In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-1319V

(to be published)

RONALD E. WHITE,	*	
	*	Chief Special Master Corcoran
Petitioner,	*	Filed: June 2, 2023
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Lisa Annette Roquemore, Law Offices of Lisa A. Roquemore, Rancho Santa Margarita, CA, for Petitioner.

Meghan Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On October 5, 2020, Ronald E. White filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioner alleges that an influenza ("flu") vaccine he received on November 1, 2017, caused him to incur Guillain-Barré syndrome ("GBS"). *Id.*

[1] As provided by 42 U.S.C. § 300aa-12(d)(4)(B), the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

It appeared readily evident from the record that Petitioner could likely meet the elements of a Table flu-GBS claim. But because Respondent argued that evidence supported an alternative cause for Petitioner's injury, I proposed that the parties brief the matter, with Respondent tasked with showing that (after the burden shifted) he could carry his burden. *See* Respondent's Motion, dated May 31, 2022 (ECF No. 26) ("Mot."); Petitioner's Opposition, dated August 1, 2022 (ECF No. 28) ("Opp."); Respondent's Reply, dated October 31, 2022 (ECF No. 32) ("Reply").

Now, having reviewed the above plus the filed medical records, expert reports, and associated literature, I hereby deny an entitlement award. As discussed in greater detail below, Respondent has carried his burden of demonstrating that a "factor unrelated"—namely an ongoing respiratory infection ("URI") caused by a *Haemophilus influenza* ("*H. influenza*") bacterial infection—was the more likely explanation for Petitioner's GBS.

I. Fact History

Petitioner was born on August 1, 1947. Ex. 3 at 1. Petitioner's pre-vaccination medical history included a childhood polio infection that caused chronic right lower extremity atrophy and weakness for which he wore a brace on his right leg. Ex. 1 at 38; Ex. 3 at 20. Beginning in January 2017, Petitioner also required a walker for ambulation, secondary to his post-polio weakness. Ex. 1 at 38. His history was otherwise significant for hyperlipidemia, benign prostate hypertrophy, prostatitis, gastroesophageal reflux disease, carpal tunnel, and obesity.[3] Ex. 3 at 13, 18; Ex. 4 at 63; Ex. 7 at 4, 108, 259.

Vaccination and Hospitalization

On November 1, 2017, Petitioner received a flu vaccine in his left deltoid at the office of his primary care physician ("PCP") by William Larsen, M.D. Ex. 3 at 13–17, 54. His PCP noted Petitioner's "post-polio stigmata," but did not document anything else on physical examination. *Id.* at 13–17. There is no medical record evidence of any immediate reaction to the vaccine, or close-in-time malaise or other concerns.

Thirty-four days later, on December 5, 2017, Petitioner presented to a local CVS MinuteClinic complaining of a non-productive cough, nasal congestion, runny nose, and generalized fatigue that had lasted for two days. Ex. 5 at 3–4. Petitioner had a temperature of 99.6 degrees, and on exam displayed bilateral middle ear effusions, mucosal edema and rhinorrhea, an irritated throat, and decreased breath sounds in his right middle lung field. *Id*. at 3, 5. The nurse practitioner diagnosed him with a viral infection and prescribed benzonatate, a non-narcotic cough suppressant. *Id*.

[3] In addition, both of Petitioner's parents had a significant cardiac history, and his mother had Parkinson's Disease. Ex. 4 at 8; Ex. 7 at 3980.

On December 10, 2017, Petitioner went to the Atrium Health Harrisburg Emergency Department ("ED"), complaining of generalized weakness that he reported had begun approximately ten hours earlier that same day. Ex. 7 at 143–45. Petitioner also noted ongoing URI symptoms that he said had begun ten days prior but had not improved. *Id*. at 143. Thus, Petitioner stated that he had a fever several days ago, cough, wheezing, and congestion, and was self-treating with over-the-counter medications and prescriptions. *Id*. at 143, 196. Now, however, he had more recently begun to experience increased weakness in his legs, and difficulty walking earlier that day that led to a fall. *Id.* at 143. He had a temperature of 97.9 degrees (and thus was afebrile). *Id.* at 144.

Upon examination, Petitioner displayed +2/5 motor strength in all extremities, and the physician could not elicit patellar reflexes. Ex. 7 at 144–45. A head CT showed no acute findings, and Petitioner's chest X-ray was normal. *Id*. at 147–48. Petitioner's lab work revealed an elevated white blood cell count of 12.9, with elevated absolute neutrophils of 9.7. *Id*. at 179; Ex. 1 at 338. Based upon these findings, the ED physician expressed concern about the possibility of GBS, and therefore ordered Petitioner to be transferred to a facility that had plasmapheresis capabilities. Ex. 7 at 145. But treaters continued to report Petitioner's concurrent URI symptoms, noting that he likely was experiencing a viral illness.[4] Ex. 1 at 38, 49, 146, 154, 164, 174, 184, 200, 205, 226, 228–29, 257, 268, 316.

Later that day, Petitioner was transferred to Carolinas Medical Center for further evaluation and treatment, and admitted to the intensive care unit ("ICU") for close monitoring of his respiratory status.[5] Ex. 1 at 341. Due to the rapid progression of his ascending paralysis, Petitioner's physicians expressed the concern that he might have an underlying structural abnormality, but MRI imaging of his brain and cervical spine did not confirm the existence of such issues. *Id*. at 23, 305, 314. Petitioner's lumbar puncture also did not show an elevated protein level, but given his clinical presentation he was suspected to have GBS. and was therefore started on plasmapheresis. *Id.* at 305, 314.

Cerebrospinal fluid testing performed at this time did not detect the presence of the herpes simplex virus. Ex. 1 at 466, 502. Nevertheless, throughout Petitioner's hospitalization, many of his treating physicians opined or speculated that his neurologic, GBS-like symptoms were associated with his preceding/ongoing respiratory infection. *See, e.g.*, Ex. 1 at 43 ("recent/ongoing

[4] In following years, and on a few occasions, treaters entertained the possibility that Petitioner had an allergic reaction from the vaccine, though these instances did not dispute or discuss Petitioner's URI infection. Ex. 2 at 7; Ex. 3 at 2, 5, 8; Ex. 6 at 79.

[5] An addendum was made the following day, December 11, 2017, by Samantha Dreyer, M.D., recounting the events of the day before but noting that Petitioner had reported that he suffered from a "head cold" for the past ten days, and it was thus decided that he remain in the ICU because he was at risk for respiratory compromise. Ex. 1 at 38. In this same record, however, Dr. Dreyer incorrectly noted that Petitioner had received no vaccines that year. *Id*.

URI all are highly suggestive of GBS), 200 ("bad URI 10 days prior to presentation"), 205 ("complaints of 10-day history of viral URI with onset of bilateral lower extremity weakness"), 228 (same), 241 (same), 301 ("[r]eport recent [] viral type syndrome"). No treaters at this time proposed his more recent symptoms had anything to do with the flu vaccine he had received almost six weeks before.

Despite initially responding well to plasmapheresis treatment, Petitioner's neurological condition continued to worsen, and he was intubated on December 13, 2017. Ex. 1 at 301. He was areflexic and had +1 motor strength in all extremities. *Id*. at 306. Then, on December 14, 2017, a sputum[6] sample from Petitioner's lungs was taken and the culture of it revealed an *H. influenzae* infection. Ex. 1 at 27–28. Petitioner's blood cultures were negative for bacteria, however. *Id*. at 28; Ex. 7 at 215. He had worsening chest X-ray findings in both his lungs. Ex. 1 at 451. Petitioner was given a seven-day course of IV antibiotics and a tracheostomy placed due to suspected prolonged course towards recovery. *Id.* at 144; Ex. 7 at 215.

On December 20, 2017, Petitioner was transferred from the ICU to a progressive unit for ventilator weaning. Ex. 1 at 185. His course was complicated by an ileus and two acute episodes of urinary retention. *Id*. at 7, 111. Petitioner underwent an extensive work up to rule out GBS mimics including arsenic poisoning, Lyme disease,[7] HSV, neurosyphilis, and B1 deficiency; none were deemed the cause of Petitioner's condition. *Id.* at 2–8, 26. However, throughout his hospitalization and even after his discharge, there were numerous occasions where treaters continued to repeat the hospital summary that Petitioner likely had experienced *H. influenza* pneumonia. Ex. 1 at 50, 83, 90, 102, 111, 123, 146, 165, 185, 200. Petitioner received seven total plasmapheresis ("PLEX") sessions, the last of which was completed on December 21, 2017. *Id.* at 174. Upon discharge, the differential diagnosis included GBS and *H. influenzae* pneumonia. Ex. 1 at 2.

Post-Discharge Health

Petitioner was discharged to a long-term acute care hospital on December 28, 2017, where he continued to improve. Ex. 2 at 7. On January 24, 2018, Petitioner was then transferred to inpatient rehabilitation at Carolinas Rehabilitation Northeast, showing even more progress toward better health. *Id*. at 2. He remained dependent on assistance with all movement, requiring a wheelchair for ambulation and complete assistance with transfers to and from the bed and

[6] Sputum is defined as a "matter ejected from the respiratory tract through the mouth." *Sputum,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=46835&searchterm=sputum (last visited Apr. 18, 2023).

[7] In the midst of his workup, Petitioner also underwent a Lyme draw that was borderline positive, but he had no risk factors or other clinical signs or symptoms for Lyme disease, so it was proposed that this was likely a false positive. Ex. 1 at 46–47, 88.

bathroom. *Id*. at 8. By February 16, 2018, Petitioner was still unable to feed, bathe, or groom himself, and was discharged to a skilled care facility for further care. *Id*. at 8–9. Records from this time revealed mention of his prior receipt of the flu vaccine, although they do not also include treater speculation of a GBS-vaccine association. Ex. 2 at 7, 10.

Petitioner subsequently spent three months at a different rehabilitation facility. He was discharged in May 2018, and although he had improved he required a wheelchair, hospital bed, Hoyer lift, and bedside commode for home use. Ex. 2 at 63. Through the early fall of 2018, Petitioner received home nursing care, including home physical and occupational therapy. Ex. 6 at 4–563. During one of his initial care visits (on May 28, 2018), it was reported that Petitioner had been "diagnosed with GBS after having a flu shot and about a week and a half of cold symptoms, which was associated with weakness and an overall decline in functional status." Ex. 6 at 79.

On December 6, 2018, Petitioner saw his PCP Catherine Norton, M.D., at Northwest Family Physicians for a yearly physical exam. Ex. 3 at 7. Dr. Norton noted that Petitioner still wore a right leg brace for his post-polio syndrome and continued to have sequelae from GBS (which the record states he developed after a flu vaccine two years prior). *Id.* Dr. Norton did not conduct a musculoskeletal or detailed neurological exam as part of her assessment. *Id.* at 7–12.

On March 25, 2019, Petitioner returned to Northwest Family Physicians for a productive cough and was diagnosed with bronchitis. Ex. 3 at 4–6. At that time, Petitioner was unable to stand on his own for longer than a few seconds and required a hospital bed for a change in position, ability to prevent decubitus ulceration, and facilitate getting in and out of bed for adequate sleep. *Id.* He also needed a wheelchair for ambulation. *Id.*

In August of 2019, Petitioner suffered a heart attack and underwent a coronary bypass surgery at Carolinas Medical Center, where he was admitted from August 13-September 5, 2019. Ex. 7 at 3926–27. Petitioner was noted to have worsened left upper extremity weakness following surgery and had a neurology consultation due to concern for post-operative stroke. *Id*. Upon examination by neurologist Paul Weaver, D.O., he found Petitioner to have +5/5 bilateral upper extremity and left lower extremity motor strength and +4/5 right lower extremity strength. *Id*. at 3980. Dr. Weaver noted that Petitioner had a history of GBS "secondary to *H. influenza*." *Id*. at 3979. Petitioner's head CT was negative for acute findings and the neurology service felt that Petitioner had no findings significant for an acute stroke, nor did he have worsened deficits. Dr. Weaver recommended that Petitioner wean his narcotics usage and recommended rehabilitation to increase his strength following hospitalization. *Id.* at 4000.

On September 19, 2019, Petitioner saw cardiologist Kiran Venkatesh, M.D., for follow up after his bypass surgery, and no musculoskeletal complaints were documented at this visit. Ex. 7

at 6567. Petitioner received home care from Bayada Home Health Care from October 24, 2019 through December 17, 2019 for occupational and physical therapy to increase his strength following his hospitalization for bypass surgery. Ex. 6 at 570–739. As of 2020, Petitioner was regularly being treated for diabetes by Peter Nguyen, D.O., at Harrisburg Family Physicians. Ex. 7 at 28–29; Ex. 8 at 68–72. It is not evident from these later records whether Petitioner by this time continued to suffer from the effects of his previously-diagnosed GBS.

II. Expert Reports

A. *Petitioner's Expert – Lawrence Steinman, M.D.*

Dr. Steinman, a neurologist, prepared two written reports for the Petitioner.[8] Report, dated October 1, 2021, filed as Ex. 9 (ECF No. 22-1) ("Steinman First Rep."); Report, dated August 1, 2022, filed as Ex. 32 (ECF No. 27-1) ("Steinman Second Rep."). Given the nature of the parties' dispute, the most relevant portion of his opinion related to questioning the role Petitioner's *H. Influenza* infection could have played in causing his GBS. Steinman First Rep. at 1.

As shown in his CV, Dr. Steinman received his undergraduate degree from Dartmouth College, and his medical degree from Harvard Medical School. *Curriculum Vitae,* filed as Ex. 10 on October 1, 2021 (ECF No. 22-2) ("Steinman CV") at 1. He then completed residencies in neurology and pediatrics at Stanford University. *Id.* He has worked as a professor of neurology and pediatrics at Stanford for the past 41 years. *Id.*; Steinman First Rep. at 2. He is board certified in neurology from the American Board of Psychiatry and Neurology. Steinman CV at 2. Dr. Steinman has also published hundreds of peer-reviewed publications on neurology and autoimmune disease. *Id.* at 5–49. He holds several patents related to the diagnosis and treatment of autoimmune and demyelinating diseases. *Id.* at 2–3. He presently serves as the George A. Zimmerman Professor of Neurological Sciences, Neurology, Genetics and Pediatrics at Stanford University. *Id.* at 1.

First Report

Dr. Steinman began his report with a summary of the medical records, accepting Petitioner's GBS diagnosis. Steinman First Rep. at 4–7. He then outlined the scientific theory of molecular mimicry and its relevance to GBS's mechanistic process. *Id.* at 7–8, 10; *see* L. Steinman, *Autoimmune Disease*, Scientific Am. 106, 109 (1993), filed as Ex. 17 (ECF No. 22-9) ("Steinman

[8] Dr. Steinman's two filed reports totaled 34 pages—comparatively less than what he has prepared in many other cases. However, Dr. Steinman has a long-standing propensity for cutting and pasting sections taken wholesale from earlier reports, and thus repeating points not always specific to the case at hand. *See*, *e.g.*, *Trollinger v. Sec'y of Health & Hum. Servs.*, No. 16-473V, 2023 WL 2521912, at *3 n.7 (Fed. Cl. Spec. Mstr. Feb. 17, 2023), *mot. for review docketed* (Fed. Cl. Mar. 17, 2023). *Pierson v. Sec'y of Health & Hum. Servs.*, No. 17-1136V, 2022 WL 322836, at *12–13 (Fed. Cl. Spec. Mstr. Jan. 19, 2022) (copying sections from prior reports); *Gross v. Sec'y of Health & Hum. Servs.*, No. 17-1075V, 2022 WL 9669651, at *15–18 (Fed. Cl. Spec. Mstr. Sept. 22, 2022) (same). He has done so once again in this case.

I") (sharing how structures on a virus or bacteria or in a vaccine can trigger a cross-reactive response to the self); *see also* S.S. Ahmed et al., *Antibodies to Influenza Nucleoprotein Cross-React with Human Hypocretin Receptor 2*, 7 Sci. Translational Med. 1, 1 (2015), filed as Ex. 18 (ECF No. 22-10) (describing the role of molecular mimics in the flu vaccine and narcolepsy). He also discussed what degree of homology between viral amino acids and myelin basic protein - the anticipated situs of attack for a demyelinating condition—would be necessary to support his theory, as well as some specific amino acid sequences likely involved. Steinman First Rep. at 11–21. (Because this case does not turn on the capacity of the flu vaccine to cause GBS, I do not include an extensive review of this aspect of Dr. Steinman's opinion).

Dr. Steinman next considered record evidence pertaining to the dual or competing roles of the vaccine and *H. influenza* in Petitioner's injury. Steinman First Rep. at 22. Dr. Steinman opined that Petitioner's GBS was more likely caused by his flu vaccination. *Id.* He acknowledged that the *H. influenza* infection might be causally associated with GBS. *Id*. at 9; Y.Y. Ju et al., *Haemophilus Influenzae as a Possible Cause of Guillain–Barre´ Syndrome*, 149 J. Neuroimmunology 160, 160 (2004), filed as Ex. 19 (ECF No. 25-20) ("Ju") ("there is a possible but rare association of GBS with nonencapsulated *H. influenzae* in the UK"). But even assuming Petitioner experienced a wild *H. Influenza* infection prior to his GBS onset (something he maintained was unclear from the records) the flu vaccine was still likely *also* a substantial factor in Petitioner's injury (although offered this assertion in conclusory form). *Id.*

One point Dr. Steinman made in regard to infection causality was the existence of record ambiguity about the extent or scope of a pre-onset infection. Petitioner's medical records clearly noted his vaccination, and on some occasions (reported months or years after the onset of symptoms), treaters entertained the possibility of some vaccine-injury association or that it provoked some allergic reaction. Ex. 2 at 7; Ex. 3 at 2, 5, 8; Ex. 6 at 79. By contrast, though tests revealed the presence of *H. influenza* in the Petitioner's sputum, blood cultures had not also confirmed its existence. Steinman First Rep. at 9, 22–23; Ex. 7 at 215. Dr. Steinman also noted that the sputum cultures were not confirmed as positive until December 14th—*after* Petitioner was already hospitalized with GBS, further casting doubt on the role of the *H. influenza* infection in relation to Petitioner's GBS. Steinman First Rep. at 9, 22–23. Dr. Steinman did not, however, comment on or discuss the record evidence that (*prior* to the sputum testing) Petitioner had been sick with some kind of infection—and that these symptoms unquestionably pre-date GBS onset.

Second Report

Dr. Steinman's Second Report spent additional time defending the putative GBS-flu vaccine association, as well as his methodology used to test it. Steinman Second Rep. at 2–7. But he also addressed in some greater detail the more central question of whether Petitioner's *H. Influenza* infection could have been causal of his GBS. He again acknowledged the possibility that

H. influenza might be a factor, referencing his citation to Ju. Steinman Second Rep. at 1; Ju at 166. However, he opined that *H. influenza* was only *rarely* associated with GBS—whereas the flu vaccine is "presumed causative" of GBS (at least in the context of a Table claim). Steinman Second Rep. at 1. He also maintained that one of Dr. Collins's references acknowledged a possible small increased risk of GBS follow receipt of the flu vaccine. F. DeStefano et al., *Principal Controversies in Vaccine Safety in the United States*, Clinical Infectious Diseases 1, 4 (2019), filed as Ex. A-9 (ECF No. 25-10) ("DeStefano"). DeStefano is a review article that summarizes findings about what it deemed "the main current vaccine safety controversies in the United States," including the flu vaccine-GBS association. DeStefano at 1. However, although DeStefano's authors agreed that some vaccine-GBS association has been found, it characterized the association/risk as "small and *less than the increase in risk following natural influenza infection*." *Id.* at 4 (emphasis added). DeStefano makes no mention of any *H. influenza* wild infection risk.

In addition, Dr. Steinman reiterated his argument that the evidence Petitioner had even experienced an *H. Influenza* infection was weak. Here, the lab results confirming the existence of an *H. influenza* infection were obtained post-hospitalization and remained "ambiguous," leaving the unquestionable fact of the flu vaccine as the likely cause of Petitioner's GBS. Steinman Second Rep. at 7. Even if an *H. influenza* infection might play a role in causing GBS, the vaccine remained a substantial factor in this case, without which Petitioner would not likely have experienced GBS. *Id.* In fact, Dr. Steinman maintained that both the *H. influenza* and flu vaccine could very well have combined to cause a "synergistic effect." *Id.*

B. *Respondent's Expert – Kathleen L. Collins, M.D., Ph.D.*

Dr. Collins submitted two expert reports on behalf of Respondent. Report, dated as February 11, 2022, filed as Ex. A (ECF No. 25-1) ("First Collins Rep."); Report, dated as November 29, 2022, filed as Ex. C (ECF No. 33-1) ("Second Collins Rep.").

Dr. Collins received her undergraduate degree from Wellesley College, and her medical and doctorate degrees from John Hopkins University School of Medicine. *Curriculum Vitae,* filed as Ex. B on February 11, 2022 (ECF No. 25-24) ("Collins CV") at 1. She then had postdoctoral training in Internal Medicine at the Brigham and Women's Hospital, Infectious Disease Clinical Fellow, Research Fellow at Harvard University, and a Postdoctoral Fellowship at the Massachusetts Institute of Technology. *Id.* Dr. Collins has been a faculty member at the University of Michigan's Medical School since 1998, where she teaches on internal medicine. *Id.*; Collins First Rep. at 1. She is board certified in infectious disease. Collins CV at 7. She also runs a research laboratory at the University of Michigan that studies molecular mechanisms of human immunodeficiency virus ("HIV") persistence and has over 70 publications on the topic. *Id.* at 15–21; Collins CV at 1.

First Report

Dr. Collins summarized the pertinent medical records before giving her primary opinion. Collins First Rep. at 2–5.[9] She acknowledged that GBS attributable to the flu vaccine, as alleged here, is an accepted Vaccine Injury Table claim. Collins First Rep. at 6–8. But numerous studies have examined the risk of GBS following receipt of the vaccine, with results demonstrating that the risk is significantly less than that following an acute respiratory infection. *Id*. at 6-8; C. Tam et al., *Guillain-Barre´ Syndrome and Preceding Infection with Campylobacter, Influenza and Epstein-Barr Virus in the General Practice Research Database*, 2 PLoS One 1, 5 (2007), filed as Ex. A-4 (ECF No. 25-5) ("Tam") (reporting evidence of a protective effect of the flu vaccination on GBS risk, and confirming associations between infection due to influenza-like illnesses and GBS (along with other types of infections)). Other evidence of the infection/GBS association was referenced by Dr. Collins and deemed equally reliable and persuasive. Collins First Rep. at 8–10. For example, *Campylobacter jejuni*[10] infections are commonly discussed in association with cases of GBS.[11] Collins First Rep. at 8–9. As Dr. Collins noted, Tam observed that a recent prior infection of *C. jejuni* had been reported in 26-60 percent of GBS cases, and thus there was up to a 60-fold increased risk of GBS after a *C. jejuni* infection. Collins First Rep. at 9; Tam at 5.

More relevant to this case, Dr. Collins cited literature supporting the contention that *H. influenzae* can also cause the kind of acute respiratory infections that increase the risk for developing GBS. Collins First Rep. at 10; Ju at 165–66 (determining that six GBS patients had elevated anti-*Haemophilus influenzae* antibodies compared with only one in normal controls, suggesting a possible association); M. Mori et al., *Haemophilus Influenzae Infection and Guillain–Barre´ Syndrome*, 123 Brain 2171, 2171 (2000), filed as Ex. A-20 (ECF No. 25-21) ("Mori")

[9] Just as Dr. Steinman devoted much of his first report to discussing things not really in dispute, such as the capacity of the *flu vaccine* to cause GBS (and specifically how), Dr. Collins offered testimony and evidence to rebut that association. Collins First Rep. at 11-12. But these aspects of her reported opinion need not be exhaustively evaluated, since (as I have already observed) the case's resolution turns far more on whether the *H. Influenza* wild infection can cause GBS, and more likely did so here.

[10] Dr. Collins defined *Campylobacter jejuni* as a bacterial pathogen that causes a gastrointestinal illness in humans. Collins First Rep. at 8.

[11] The GBS variant most associated with *C. jejuni* is acute motor axonal neuropathology ("AMAN"). Collins First Rep. at 9. Through molecular mimicry, it is thought that an abnormal antibody response against *C. jejuni* cross reacts with components of nerve axons to cause AMAN. *Id*.; A. Hahn, *Guillain–Barre Syndrome*, 352 Lancet 635, 635–36 (1998), filed as Ex. A-14 (ECF No. 25-15); P. van Doorn et al., *Clinical Features, Pathogenesis, and Treatment of Guillain-Barré Syndrome*, 7 Lancet 939, 941 (2008), filed as Ex. A-15 (ECF No. 25-16); N. Yuki et al., *Carbohydrate Mimicry Between Human Ganglioside GM1 and Campylobacter jejuni Lipooligosaccharide Causes Guillain-Barre Syndrome*, 101 Proceedings Nat'l Acad. Sci's 11404, 11405–06 (2004), filed as Ex. A-16 (ECF No. 25-17). This cross reaction was proposed due to a linkage between AMAN to antibodies that recognize a complex lipid called monosialoganglioside. N. Yuki et al., *Animal Model of Axonal Guillain-Barre Syndrome Induced by Sensitization with GM1 Ganglioside*, 49 Annals Neurology 712, 716 (2001), filed as Ex. A-17 (ECF No. 25-18). Another type of GBS, acute inflammatory demyelinating polyradiculoneuropathy, is less understood but can also be associated with *C. jejuni*. Collins First Rep. at 9; Tam at 1.

(finding elevated anti- *H. influenzae* antibodies in 13 percent of GBS patients, but not in any of the other two control groups); S. Nafissi et al., *The Role of Cytomegalovirus, Haemophilus Influenzae and Epstein Barr Virus in Guillain Barre Syndrome*, 51 Acta Medica Iranica 372, 375 (2013), filed as Ex. A-21 (ECF No. 25-22) ("Nafissi") (concluding that 82.9 percent of cases had an *H. Influenza* or EBV infection preceding GBS, as compared to 29 percent of the control; respiratory and gastrointestinal infection was found in 57.1 and 20 percent of cases, respectively).

By contrast, the risk from vaccination was routinely deemed lesser, even if it existed as well. *See, e.g.*, J. Stowe et al., *Investigation of the Temporal Association of Guillain-Barre´ Syndrome with Influenza Vaccine and Influenza like Illness Using the United Kingdom General Practice Research Database*, 169 Am. J. Epidemiology 382, 385–86 (2008), filed as Ex. A-5 (ECF No. 25-6) ("Stowe") (epidemiologic study looking at three risk periods (0-30 days, 31-60 days, and 61-90 days) after vaccination or influenza like infection derived from UK data from 1990 to 2005, finding no evidence of an increased risk of GBS after the seasonal flu vaccine); L. Grimaldi-Bensouda et al., *Guillain-Barre´ Syndrome, Influenza like Illnesses, and Influenza Vaccination During Seasons with and Without Circulating A/H1N1 Viruses*, 174 Am. J. Epidemiology 326, 326 (2011), filed as Ex. A-6 (ECF No. 25-7) ("Grimaldi-Bensouda"). Grimaldi-Bensouda examined all incidents of GBS cases meeting broadly-accepted classification criteria that were diagnosed at 25 neurology centers in France between March 2007 and June 2010, concluding there were no concerns regarding GBS risk from modern flu vaccination. Collins First Rep. at 6–7.

Based on the above, Dr. Collins maintained that it was more likely than not that a prior infection evident from this record had caused Petitioner's GBS. Collins First Rep. at 10. She notes that Mr. White experienced an acute respiratory infection with a ten-day history of symptoms *prior* to the development of his neurological symptoms. *Id*. He displayed an elevated white blood cell count and an abnormal chest X-ray, and science associates respiratory infection by a bacterial pathogen (*H. influenzae*) with GBS. Collins First Rep. at 10. In addition, on numerous occasions treaters stated that Petitioner had likely experienced *H. influenzae*-caused pneumonia. Collins First Rep. at 11; Ex. 1 at 50, 83, 90, 102, 111, 123, 146, 165, 185, 200.

Dr. Collins did not deem Dr. Steinman's contrary opinion to be persuasive. Collins First Rep. at 10–12. First, she took issue with his contention that the lack of blood testing confirmation of the presence of an *H. Influenza* infection undermined the positive sputum findings. Collins First Rep. at 11 (discussing Steinman First Rep. at 22–23). In so doing, Dr. Collins underscored her expertise in the study of infectious disease, maintaining that Dr. Steinman's weighing of these items of evidence was in error (especially since his experience is in neurology). Collins First Rep. at 11. A patient suffering from pneumonia would not be *expected* to have positive blood cultures, she argued, and the negative findings merely established that the infection had not spread to his blood. Collins First Rep. at 11. By contrast, evidence of growth of *H. influenzae* plus the presence of bacteria and white blood cells observed in the lung specimen under the microscope by gram

stain stood as more conclusive evidence of Petitioner's *H. influenzae* bacterial infection. Collins First Rep. at 11. And the diagnosis of pneumonia was further supported by chest X-ray findings revealing worsening in both his lungs. Collins First Rep. at 11; Ex. 1 at 451.

Second, Dr. Steinman had referenced record statements by two treaters suggesting that Petitioner was allergic or had a contraindication to the flu vaccine, but Dr. Steinman had not also pointed to evidence that Petitioner had signs of any allergic response in the first place. Collins First Rep. at 12. In contrast, at least 14 treaters associated Petitioner's upper respiratory infection with the development of his GBS. Collins First Rep. at 12; Ex. 1 at 38, 49, 146, 154, 164, 174, 184, 200, 205, 226, 228–29, 257, 268, 316. The weight of treater views clearly favored the infection over vaccination as causal.

Dr. Collins concluded by commenting on onset timing, offering the opinion that Petitioner likely acquired the *H. influenzae* infection *before* he was hospitalized with GBS. Collins First Rep. at 11. She interpreted the record to be consistent with the infection beginning as an upper respiratory infection (documented prior to the development of weakness) but subsequently developing into a *lower* respiratory infection over time. Collins First Rep. at 11. *H. influenzae* is a relatively common cause of both upper and lower respiratory infection, but uncommonly associated with pneumonia acquired *after* hospitalization.[12] Collins First Rep. at 11. And the record clearly established that he had an *upper* respiratory infection for ten days prior to developing GBS. Collins First Rep. at 10. The fact that the sputum culture that revealed the infection was performed after Petitioner's GBS onset was not evidence that the infection itself *followed* GBS, given the ample evidence from before onset of neurologic symptoms that he was already suffering from a respiratory infection (*e.g.,* nasal drainage, subjective fevers, cough, congestion, fluid in the middle ear, and an elevated white blood cell count). *Id.* at 11; Ex. 1 at 338; Ex. 5 at 3–5; Ex. 7 at 143, 179.

Second Report

Putting aside arguments aimed at Dr. Steinman's causation theory that do not help resolve the parties' dispute, Dr. Collins again emphasized literature she had offered demonstrating that acute respiratory infections (including those caused by *H. influenza*) are strongly associated with GBS. Collins Second Rep. at 2. These items (which she noted Dr. Steinman had not discussed) outweighed articles underscoring a vaccine-GBS association, like DeStefano. *Id.* (referencing Nafissi at 375 and Mori at 2171). She also reiterated her prior point that the flu vaccine-GBS association was weaker than Petitioner proposed. Collins Second Rep. at 2–3 (references omitted). There was thus in her view more reliable evidence for an association between an upper respiratory

[12] In addition, Dr. Collins addressed a reference from the medical records potentially suggesting a post-GBS onset ("with GBS and now pneumonia,"(Ex. 7 at 607)). She argued the citation merely referred to the timing of the *lower* respiratory lung infection. Collins First Rep. at 10. I have not, however, been able to locate the referenced cite.

infection by a bacterial or viral pathogen (*H. influenza*) and GBS than between the illness and the flu vaccine. Collins Second Rep. at 1, 4.

In addition, Dr. Collins again reviewed record evidence of the time course, signs, and symptoms of Petitioner's infection that she proposed had led to his injuries. Collins Second Rep. at 1; Collins First Rep. at 11. Dr. Steinman had not, in her estimation, adequately addressed this evidence (as well as the fact that overwhelming treater support suggested the infection was causal). Collins Second Rep. at 2. And even if the Vaccine Program recognized a *claim* for GBS as a flu vaccine injury, in the context of this case—where a competing, alternative explanation was so evident from the record—the existence of a Table claim did not make it more likely per se the vaccine was causal. On the contrary, she had offered evidence *undermining* the vaccine-GBS association, and it was relevant to this case (since it suggested that in the context of dueling causes, the evidence supporting a flu vaccine association was weaker than it appeared). *Id.*

III. Procedural History

After the case's initiation in October 2020, this matter was originally assigned to SPU, since it appeared to assert a flu-GBS Table claim (and thus potentially could be resolved quickly if the claim met the Table elements). Petitioner filed medical records supporting the claim, and then Respondent's Rule 4(c) Report was filed on April 2, 2021 (ECF No. 14). It was thereafter transferred out of SPU, because it was determined that the parties would likely require the use of medical experts to address the issue of causation and/or to determine whether the flu vaccination was a substantial factor in causing Petitioner's GBS. ECF No. 15.

The case was assigned to my non-SPU docket, then to another special master, and then back to me in the spring of 2021. Petitioner and Respondent then filed some of the expert reports discussed above. ECF Nos. 22, 25. Thereafter I set a briefing schedule on the "factor unrelated" issue, and dates for any final expert reports. *Scheduling Order*, dated February 17, 2022. The parties had fully briefed the matter and filed supplemental expert reports by November 2022, and it is now ripe for resolution.

IV. Parties' Arguments

Petitioner argues that he has met his *prima facie* burden of demonstrating a Table Injury[13]—he received a flu vaccine, experienced GBS, and his onset fell within three to 42 days of vaccination. Opp. at 19, 23. The only remaining issue was whether Respondent had met his

[13] Even if Petitioner did not meet the Table requirements, he asserts that he still meets all three *Althen* prongs for a non-Table case. Opp. at 23–24, 26.

burden of establishing a factor unrelated to the flu vaccine—something Petitioner denied had occurred. *Id.* at 19.

Petitioner maintains that Respondent must show by a preponderance of the evidence that the *H. influenzae* was the "*sole and substantial cause* and how the [flu] vaccine *had nothing* to do with the GBS." *Id.* at 19, 25; *Shyface v. Sec'y, Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). But Respondent could not exclude the vaccination completely as a causative factor. Instead, he relied on the contention that it was statistically more probable that the infection caused his injuries. Opp. at 21, 23, 26. But Respondent had not proposed a theory for how the infection causes GBS, or how it caused Petitioner's injuries in particular. *Id.* at 22. Petitioner also argued that the record did not permit the conclusion as to when the *H. influenzae* infection likely commenced, as his blood culture was not sampled until four days after he was hospitalized, and his prior symptoms could simply have been the product of a "head cold." *Id.* at 24, 26, 28. Thus, Respondent failed in addressing how the vaccine had "zero impact" on Petitioner's GBS. *Id.* at 19, 22.

In opposing entitlement, Respondent argues that Petitioner's GBS was caused by a factor unrelated to his flu vaccination—the *H. influenzae* infection. Mot. at 16; Reply at 6. The medical literature demonstrates that the risk of GBS following infection is much higher than following vaccination, and thus it has been shown that this kind of infection "can cause" GBS. Mot. at 11–14; Reply at 8. For the logical sequence of cause and effect/"did cause" prong, Respondent maintains that the medical records establish that Petitioner acquired the *H. influenzae* infection post-vaccination, had an onset of GBS ten days after prolonged and objective, test-substantiated documentation of a URI, and then subsequently was diagnosed with *H. influenzae* pneumonia. Mot. at 10–11; Reply at 2. Respondent does not give weight to Petitioner's argument of a single notation discussing a "head cold," as the countervailing weight of the evidence demonstrates that Petitioner had a URI leading up to his hospitalization. Reply at 2–4.

In addition, Respondent notes that the vast majority of Petitioner's treaters attributed his GBS to his URI rather that the flu vaccine. *Id.* at 5–6; Mot. at 15–16. By contrast, the one treater who attributes the flu vaccine to Petitioner's GBS, Dr. Norton, erred in his determination. Mot. at 15–16. This treater view is expressed in a record generated a full year after Petitioner's diagnosis (not during his treatment). In addition, Dr. Norton's assessment had other inaccuracies regarding Petitioner's GBS course. *Id.* Petitioner cites to another medical record that discusses a flu vaccine and his cold symptoms before his GBS diagnosis, but this documentation was made by a physical therapist's evaluation six months after his hospitalization. Reply at 5. And otherwise these treater views seem reliant on the temporal association between vaccination and GBS. *Id.* At bottom, Respondent argues that based on a preponderance of the evidence, Petitioner's *H. influenzae*

infection most likely caused his GBS—but for his infection, Petitioner would not have developed GBS.[14] Mot. at 17; Reply at 6, 8–9.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[15] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason

[14] Respondent does not discuss *Shyface* in his briefs, or this argument that he must prove the unrelated factor is the "sole and substantial cause" of Petitioner's injury to meet his burden.

[15] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)); *Howard v. Sec'y of Health & Hum. Servs.*, No. 16-1592V, slip op. at *6 (Fed. Cl. Feb. 27, 2023) (confirming that "[t]he standard has been preponderance for nearly four decades"). Otherwise, petitioners *always* have the ultimate burden of establishing their Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d

at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required

to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health*

& Hum. Servs., 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs*., 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for

controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical

literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, and the parties have not challenged my determination to do so. Mot. at 1; Opp. at 1. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Petitioner Has Met His Prima Facie Burden of Proof for a Table Flu Vaccine-GBS Claim

The parties agree that Petitioner has alleged a Table claim in this case. Mot. at 13 n.3; Reply at 6. GBS is listed as a Table injury for the flu vaccine, and thus a claimant seeking to meet its requirements must show (a) receipt of a covered form of the flu vaccine, (b) that the claimant did in fact experience GBS as defined in the Table's "qualifications and aids to interpretation," and (c) that onset (whether or not GBS could then be diagnosed, or was) occurred between three and 42 days after vaccination. 42 C.F.R. § 100.3.

Here, all of these elements exist and/or have been satisfied. There is no dispute that Petitioner received the flu vaccine, and his GBS diagnosis is not contested. Moreover, his onset was most likely on December 10, 2017, when he first sought treatment for bilateral upper and lower extremity weakness that he reported had begun approximately ten hours earlier that same

day, Ex. 7 at 143. An onset 39 days post-vaccination falls within the timeframe set for a successful Table flu-GBS claim. Thus, the record preponderantly supports the prima facie elements of Petitioner's Table claim—meaning that Respondent can only prevail if he carries his shifted burden to prove a "factor unrelated." Section 13(a)(1)(B).

II. Respondent Has Established That Mr. White's Condition Was Caused by an Intercurrent *H. influenza* Infection—a "Factor Unrelated" to the Flu Vaccine

The nature of Respondent's "factor unrelated" burden in this case must be accurately explained. While the evidentiary standard applicable under *Althen*, preponderance, also applies even after the burden shifts, governing authority has characterized the burden on Respondent in this context to be "higher"—or, more accurately, not literally congruent with what a petitioner must demonstrate to receive damages, with one additional obligation not placed on claimants.

When a claimant successfully establishes a prima facie case of causation, "the burden then shifts to the government to prove alternative causation by a preponderance of the evidence." *Cedillo,* 617 F.3d at 1338. The Vaccine Act defines "factors unrelated to the administration of the vaccine" to be matters "documented by the petitioner's evidence or other material in the record," such as "infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents *principally responsible for causing* the petitioner's illness, disability, injury, condition, or death." Section 13(a)(2)(B) (emphasis added).

As noted by the Court of Federal Claims in *Stone v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 233, 237 (2010),

> the standard for proving a "factor unrelated" is higher than the petitioner's burden of proving a prima facie case. Although a petitioner is required to show that the vaccine was a "substantial factor" in causing his or her injury, 'the petitioner need not show that the vaccine was the sole or predominant cause of her injury.' (*de Bazan,* 539 F.3d at 1351). The respondent's burden, by contrast, is to 'identify[ ] a particular [unrelated] factor (or factors) and present [ ] sufficient evidence to establish that it was the *sole substantial factor* in bringing about the injury.' *Id.* at 1354 (emphasis added). In order to prevail, therefore, the respondent must 'exclude[ ] the vaccine as a substantial factor.' *Id.*

Stone went on to observe that "[t]he difference between "substantial factor" and "sole substantial factor" is a meaningful one," noting that compensation could still be awarded even in cases where a factor unrelated had been shown to be substantial—but not "solely" substantial. *Stone,* 95 F.3d at 237 n.5 (citations omitted). This, in effect, describes what is sometimes referred to as a "*Shyface* analysis"—where two factors, including vaccination, are deemed potentially causal, but one cannot be found to predominate over the other. *Shyface*, 165 F.3d at 1352–53.

In applying this standard, then, to the question of whether a factor unrelated explains an injury, special masters must conclude that the factor unrelated was the "sole substantial factor"—although in so doing, the evidence deemed sufficient to reach that conclusion must only be *preponderant*, allowing the determination that it is "more likely than not" the factor unrelated was the sole substantial factor. That, in turn, leaves room for doubt (just as there is doubt in *any* preponderant determination that barely crosses the preponderant line). Thus, a finding that the vaccine has been excluded must only cross the "more likely than not" line, even if Respondent bears this obligation when petitioners never do.

In practice, special masters have found the factor unrelated burden met by Respondent based on the same mix of evidence and weighing of items of literature versus expert testimony that they encounter when considering Petitioner's obligations. To give one example, after remand of the *Stone* case (where Respondent maintained that a child's Dravet syndrome was solely due to a genetic mutation rather than vaccination), the special master was readily able to conclude under the proper standard that Respondent had met his burden, relying on a showing that included (a) the determination to give more weight to Respondent's expert testimony than Petitioner's, (b) the highly persuasive evidence of the alternative cause, and (c) an absence of record evidence that the vaccine *itself* had caused any harm to the child's brain (as would needed to have been shown to conclude the vaccine caused injury in accordance with the theory alleged). *Stone v. Sec'y of Health & Hum. Servs.,* No. 04-1041V, 2011 WL 836992. at *3 (Fed. Cl. Spec. Mstr. Jan. 20, 2011), *mot. for review den'd*, 99 Fed. Cl. 187 (2011), *aff'd,* 676 F.3d 1373 (Fed. Cir. 2012).

Importantly for present purposes, the strength of a claimant's prong one showing does not per se make it *less likely* that the proposed factor unrelated was not the sole substantial factor (although the evidence offered pro and con must still be weighed). And I am aware of no case law suggesting that the mere fact a claim exists as a Table claim—or that the Table elements were met, such that the burden has shifted—is an obstacle to Respondent successfully carrying his factor unrelated burden. Rather, Respondent's success in this regard must be evaluated by the same weighing process that applies to a petitioner's initial burden.

In this case, the record preponderantly supports Respondent's contention that Petitioner's demonstrated *H. Influenza* infection was the more likely sole substantial factor causing Petitioner's GBS, and that it precipitated injury independent of Petitioner's earlier-in-time receipt of the flu vaccine.

First, there is reliable evidence in the medical literature demonstrating an association between the risk of GBS following infection generally. Tam at 6–8; van Doorn at 941; Ju at 165–66; Mori at 2171; Nafissi at 375. Some of this evidence is in fact specific to the *H. influenza* infection, as well. Ju at 160. Dr. Steinman himself agreed to this association, even if he downplayed

it a bit. Steinman First Rep. at 9. And though Dr. Steinman cites literature that also associates vaccination and GBS, that risk is *consistently* deemed lesser in comparison (and in some studies unfounded). *See, e.g.*, DeStefano at 4. It has even been documented that vaccination might play a protective role against GBS. Stowe at 385–86; Grimaldi-Bensouda at 326. Thus, Respondent has not only offered preponderant and reliable evidence associating the relevant infection with GBS, but he has also shown that in the general context of vaccination and infection, vaccination will *usually* be less likely causal (thus helping Respondent to exclude the vaccine in this case as part of his enhanced burden to show factor unrelated).

Petitioner argues in response that Respondent's causation showing (under *Althen*'s "can cause" prong) is insufficient, maintaining that it mostly boiled down to the contention that probabilities favor infection over vaccine, without much scientific showing. Opp. at 21–23, 26. But it is well understood in the Vaccine Program that no one kind of evidence is needed to prove any of the *Althen* prongs—and thus that different combinations or mixes will prove sufficient in different contexts. Moreover, having had the occasion to resolve many cases in which a variety of vaccines are proposed to have been causal of nerve demyelinating injuries like GBS, I deem it almost beyond dispute that a *wide variety of infections*, both viral and bacterial, can likely be *as* causal, if not more, of GBS than the flu vaccine. *Bielak v. Sec'y of Health & Hum. Servs.*, No. 18-761V, 2023 WL 35509, at *30 (Fed. Cl. Spec. Mstr. Jan. 3, 2023) (noting that two thirds of GBS cases follow an antecedent infection). Indeed, the same evidence offered in this case by Dr. Steinman (unnecessarily, since the petition alleged a Table claim) to prove flu vaccine causation *expressly notes* the causal capacity of infections. Ju at 166. This is actually the bedrock of many a vaccine claim: if infection can be causal, the infection-like response vaccines elicit could logically be causal as well. Given the above, plus the evidence specific to GBS and *H. influenza* offered in this case, I easily find that this bacterial infection has been preponderantly shown to likely be causal of GBS.

Second, the medical records also establish that Petitioner's *H. influenzae* infection likely "did cause" his GBS. Petitioner experienced a URI with a ten-day history of symptoms, with treaters consistently deeming the infection as associated with his GBS, and it predated neurologic symptoms onset. Dr. Steinman maintains that the lack of blood testing confirmation reduced the likelihood of an infectious cause, but Dr. Collins, who is an expert in infectious diseases, has persuasively explained that a positive blood culture is unnecessary to confirm the presence of an *H. influenza* infection and in fact would not be expected unless the infection has spread to his blood. Collins First Rep. at 11. More conclusive evidence comes from sputum findings, which were positive, and the pneumonia diagnoses was further supported by chest X-ray findings and other evidence of the infection. Ex. 1 at 27–28; 451. Treaters overwhelmingly associated his GBS with this infection. Ex. 1 at 38, 49, 146, 154, 164, 174, 184, 200, 205, 226, 228–29, 257, 268, 316. I find this evidence and assessment persuasive.

Finally, the timeframe in which Petitioner's GBS manifested after his likely infection was medically acceptable. The medical records establish that the infection (which first manifested 10 days before Petitioner's neurologic symptoms on December 10, 2017) occurred far closer in time than vaccination—but within a timeframe that would be reasonable for an antibody-driven, adaptive immune system autoimmune process to occur. *See generally Randolph v. Sec'y of Health & Hum. Servs.*, No. 15-146V, 2021 WL 5816271, at *23 (Fed. Cl. Spec. Mstr. Nov. 12, 2021) (determining that a 12 day timeframe was medically acceptable period for how long it would take a wild infectious process to result in an adaptive immune response).

The same record also adds heft to the conclusion that the vaccine could likely be *excluded* as causal. As noted above, there is no record evidence of any close-in-time vaccine reaction. Almost five weeks thereafter passed before Petitioner first sought treatment for his infectious symptoms, which by this point were already ongoing. And then five more days elapsed before Petitioner's neurologic symptoms onset. *This medical history is not consistent with the vaccine playing even a contributory role to Petitioner's GBS.* And the mere fact that his onset fell into the temporal period set for onset under a Table claim (albeit on one extreme end of that timeframe) does not guarantee a vaccine "role," right to the end. The facts of this case tell a different story, and one that excludes the vaccine as likely causal in any way.[16]

Dr. Steinman argues that the very fact that the flu vaccine's causality is reflected in the existence of a Table claim somehow elevates the strength of reliability of the vaccine-injury association—so much so that the vaccine almost *has* to be considered to have played some role in Petitioner's injury. Second Steinman Rep. at 1. But the Vaccine Act does not create a "pre-rebuttal" context for factor unrelated circumstances, effectively preventing Respondent from ever excluding a vaccine as a factor so long as the Table elements were met (as here). At most, the Table claim only substantiates the idea that the flu vaccine "can cause" GBS. It does not prevent my determinations that (a) infections can also cause GBS, (b) *H. influenza* can cause GBS, (c) infections are more likely than vaccines to cause GBS, and (d) Petitioner's medical history lends strong support to the conclusion that the flu vaccine was not likely a factor in his GBS, whereas the intervening infection was.

Because of the above, the record also does *not* support the conclusion that the flu vaccine and *H. influenza* wild bacterial infection likely played dual roles in leading to Petitioner's GBS, with no expert truly able to differentiate them as causal. Certainly, there are cases where this is in fact the final take-away from expert views, and in such circumstances a *Shyface* approach mandates a determination for the Petitioner. *Matten v. Sec'y of Health & Hum. Servs.*, No. 12-155V, 2021 WL 5768148, at *42 (Fed. Cl. Spec. Mstr. Nov. 2, 2021) (determining that

[16] I emphasize again: this determination is the result of the preponderance standard. I conclude it "more likely than not" that the vaccine is excluded as causal. This of course leaves room for it being causal regardless, but the "fifty percent and a feather" weighing standard did not favor Petitioner.

Respondent's expert could not completely reject the role of the flu vaccine resulting in K.M.'s death instead of a parainfluenza virus, and thus finding that Respondent failed to satisfy his burden in showing an alternative cause). In such a case, causation is shown even if the vaccine is not the *predominant* factor causing illness; rather, it need only be demonstrated it was a *substantial*, "but for" factor. *Moberly*, 592 F.3d at 1321 (quoting *Shyface*, 165 F.3d at 1352–53). A vaccine could be causal of injury in association with another cause, even if neither can be identified as the more likely sole or primary cause, and as already noted petitioners are never tasked with eliminating the substantial factor in making their prima facie case.

But Dr. Collins did not concede that in this case she could not so distinguish the parallel potential causal factors. Rather, this record—which showed the existence of an intervening infection, closer in time to onset than the vaccine (received almost six weeks before onset), and corroborated to be a kind of infection that has been associated with GBS—supported the infection over the vaccine as the "but for" causal factor. And Dr. Steinman did not establish otherwise, beyond making conclusory assertions favoring the vaccine over infection, while failing largely to address the compelling record evidence that the Petitioner was likely experiencing a pre-GBS onset sickness that could have been causal.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[17]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[17] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.